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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/536,351	03/27/2000	Sreenivasa Rao Damarla	3900-003	3606

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01/06/2003

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

536351

Applicant(s)

DAMARLA et al

Examiner

NEC 6y

Group Art Unit

186-13

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/3/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-12, 14-19, 23 & 24 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12, 14-19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Receipt is acknowledged of brief of 10/3/02.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Examiner finds the 112 2nd ¶ issue of "substantially" is significantly addressed in the claim format of the 5/3/02 amendment. The amendment of 5/3/02 is entered.

Claims 14, 17, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner finds the terms "storage stable," unquantified, as indefinite, open to wide interpretation-the present application refer to a 14 day period, and sets no limit on acceptable % degradation to constitute a stable preparation to constitute a stable preparation. The claim limitations of the preferred parameters are quite clear however (claim 2, for example). The thrust of the application is presented in preferred forms, but this is not the scope of protection sought, and the minimal conditions are undefined. The same is true of the "substantially free of organic", -not only are the solvents not quantified, they are not specified-applicants' arguments of 11/20/01 addressed this concern by stating no organics were added. Examiner presumes the extracts, however, were of organics, as is normal-such as methanol, ethanol. However, Kleeberg, 5695763, incorporated by reference, at col. 2, lines 41-43, states surfactants are solvents, for Azadirachtin. So the surfactants are solvents, and vegetable oil, Examiner believes, can in fact dissolve some things. It is noted that the boiling points of the organic-solvents is not evident.

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If absence of solvent is a critical factor, support for appropriate claim language is not evident to examiner in the specification, as to applicants reliance on Hawley, see examiner reliance on that known in the chemical, and therapeutic, arts-see Milks vegetable oil solvents, p.260, 26.

Clearly in the examples, no organic solvent, per applicants' arguments, is added. That's not claimed. Neither is there language to the exclusion or non-use, of solvent extraction.

Claims 1, 14^{1b} are rejected under 35 U.S.C. 102(b) as being anticipated by Butler 5352697.

Butler clearly enhances Azadirachtin and Azadirachtin derivative storage stability using epoxidized vegetable oils (col.3, line 52-col. 34, line 59,); while added surfactant promotes uniform dispersion (col. 5, line14-line 33) of storage stable formulation no water is present in the blends of Azadirachtin, vegetable oil and Mon-ionic surfactants (col. 5, line 14-62 and tab 62 blend 2,3). Surfactants are 0.2-50%, Azadirachtin 0.1-85% (col.6, lines 30-33).

Applicants' arguments that there is no lack of water in Butler are seen as not as significantly better than applicants'; Butler no place adds water, except for comparison in examples 3 and 4. We do not doubt the Gopinathan declaration; we doubt its' relevance to the cited prior art.

Claims 1, 14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al 5124349. See col.4, top: Azadirachtin, 40% Neem oil, a vegetable oil, and 1-10% surfactant, no water specified; thus, claim 1 of applicant. Preferably less than 1%

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water is present (col. 3, lines 35-54); it must be removed to enhance storage stability.

Preferred surfactants are the instant Tweens-Table IV, showing both Azadirachtin A and B.

Claims 1, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimetry et al 97 and Carter et al 5124349.)

Dimetry shows Neem, with 1, 5% Azadirachtin (p.396, col. 1) and Nonionic Emulsifier, Tween 20, was enhanced in efficacy with added Sesame oil (col. 2, p. 396, bottom). No concern with stability was addressed. Carter shows stability is decreased in aqueous solution and in protoc solution (col. 1, lines53-56). (Arter also utilizes surfactants, 1-10%, to provide storage stability of Azadirachtin over 1 year (col. 2, lines 18-40). Aprotic Solvents, or carriers, are not critical (col. 3, top). Example 2 shows Azadirachtin A, Neem oil, and the instant surfactant, Tween 20 .8% (E) water retained over 2 times the % of Azadirachtin A compared to higher water content sampler (A, D, Table II).

No mention was made of Sesame oil. It would have been obvious to one of ordinary skill in the art of Natural compound Insecticidal practice, to utilize Demetry's showing of enhanced efficacy of the well known Neem, with active Azadirachtins, combined with sesame oil, absent water, as shown advantageous by Carter.

Both references recognize efficacy of Azadirachtins and Neem. Motivation of artisan to use sesame is clear; the effects would be greater, or, the amount of active could be reduced, thus saving money on expensive actives over oil, and reducing exposure to non-target species.

Motivation to use nonionic surfactants is self-evident; both references use them. The sesame oil would serve as a carrier/solvent for Carter that enhances efficacy. Stability would be as instantly claimed, since the same compositions are present.

Applicant's arguments filed 5/3/02 and brief of 10/3/02 have been fully considered but they are not persuasive. Applicant's arguments have been considered in the rejections as maintained. The rejections absent were overcome as argued and by amendment. However, the prior art still is seen as precluding allowance. The declaration shows comparison of aqueous to non-aqueous- Carter states stability decreases in water, and provides 80% stability for a year.

Claims 2-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 28 day storage, does not reasonably provide enablement for 90% for 1 year. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, without excessive experimentation.

If requested examiner will grant interview.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 308-2468. The fax phone numbers for the organization where this application or proceeding is assigned are 308-4556 for regular communications and 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy/T.G.D.
December 26, 2002

A handwritten signature in black ink, appearing to read "Neil S. Levy". The signature is written in a cursive, flowing style with a large initial "N".

NEIL S. LEVY
PRIMARY EXAMINER